DETAILED ACTION

This office action is in response to a communication dated 2/26/2010. Claims 1-3, 5-16, and 19-20 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-3, 5-9,16, and 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Strecker (US 6,416,522)** in view of **Makower et al. ("Makower" US 2001/0039426)**.

Regarding Claim 1, 16, and 19-20, Strecker discloses a fixation system for fixing an implantable device in a body cavity, comprising: an implantable device (80, 87); a plurality of resilient delivery members movable between a generally longitudinal delivery position and a radially expanded deployment position (93), the delivery members defining a delivery channel therein with a distal opening, each delivery

member having a distal end formed with a blunt profile adapted to engage the implantable device (Fig 12); a fixation component slidably disposed in each of the delivery channels (95); and a pusher slidably disposed in each of the delivery channels to push the fixation component in each delivery channel (98).

Strecker discloses that the graft is positioned in a folded configuration (Column 10, Lines 17-20) prior to expansion and the fixation components are “spaced from each other" (Column 2, Lines 2, Lines 31-33). It would have been inherent or obvious that the fixation components were equally spaced around the periphery of the vascular graft to reduce the slack in the graft and optimize the tension. Each fixation components either inherently or obvious “cooperate” with a fold of the graft because they are used to assist the expand the graft (Column 10, Lines 17-24) and secure it to the vessel wall.

Strecker discloses in a separate embodiment the tab and slot which provides a disconnectable connection between the fixation component and the pusher (Figure 15 Items 103 and 107). The Examiner also notes that tab and slot configurations are well known in drivers, the most common being a screw driver. Essentially, the pusher is guiding the anchor into place. A tab and slot configuration is old and well known to aid in the control of the anchor by the pusher. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's pusher and anchor to include a tab and a slot as is known in the art. Such a modification aids in controlling the anchor with the pusher.

Strecker discloses that the graft is positioned in a folded configuration (Column 10, Lines 17-20) prior to expansion and the fixation components are “spaced from each

other" (Column 2, Lines 2, Lines 31-33). It would have been inherent or obvious that the fixation components were equally spaced around the periphery of the vascular graft to reduce the slack in the graft and optimize the tension. Each fixation components either inherently or obvious “cooperate” with a fold of the graft because they are used to assist the expand the graft (Column 10, Lines 17-24) and secure it to the vessel wall.

Strecker does not disclose each fixation component comprises: a first fixation member; a second fixation member; and a tether connecting the first and second fixation members. **Strecker** also does not disclose each of the delivery members having a longitudinal slot communicating with an exterior of the delivery member and extending a length of the delivery channel, wherein the tether passes through the longitudinal slot of the delivery members.

However, **Makower** teaches of a similar device intended to secure a vascular graft to the inner wall of a vessel comprising a slotted delivery member **204** and first and second fixation members **209** connected by a tether **214** (Fig 27 and Paragraphs 95-99). Given the teachings of **Makower**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the fixation members of **Strecker** with a tether in order to secure the graft against the tissue and prevent “endoleaks” (Paragraph 96). It also would have been obvious to one of ordinary skill in the art at the time of the invention to modify the delivery members of **Strecker** with the slots in order to accommodate the tether. The delivery members of both **Strecker** and **Makower** are intended to guide the fixation members into tissue, so it would have been obvious that the delivery members would be proximal to the tissue that the delivery members

penetrate and that the tether would extend through the slots when the fixation members penetrate the tissue.

Regarding Claim 2, Strecker discloses the fixation system of claim 1 and further comprising: a delivery sheath slidable over the plurality of resilient delivery members (89).

Regarding Claim 3, Strecker discloses the fixation system of claim 1 wherein the delivery members define the delivery channel as a closed lumen therein with the distal opening (Fig 12).

Regarding Claim 5, Strecker discloses the fixation system of claim 1 wherein the delivery members, when in the deployed position, urge the implantable device against a wall of the body cavity (Fig 13).

Regarding Claim 6, Strecker discloses the fixation system of claim 5 wherein the first fixation member is disposed to pierce the implantable device and a wall of the body cavity when advanced from the delivery channel by the pusher (Fig 13).

Regarding Claim 7, Strecker discloses the fixation system of claim 6 wherein the first fixation member has a sharpened end for piercing the implantable device and body cavity wall (95).

Regarding Claim 8, Strecker discloses the fixation system of claim 6 wherein the first and second fixation members are arranged in a generally longitudinally aligned orientation when in the delivery channel (Fig 14).

Regarding Claim 9, Strecker discloses the fixation system of claim 8 wherein one of the first and second fixation members are releasably connected to the pusher (Fig 12).

4. **Claims 10-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Strecker** in view of **Miller (WO 02/17797)** and **Mackower**

Strecker in view of **Mackower** disclose the invention substantially as claimed as stated above but does not disclose of an inner sheath, a releasable fixation member, and an expandable member at the distal end of the sheath.

Miller teaches an inner sheath, the plurality of delivery members being arranged generally radially about the inner sheath (Fig 12 Item 210), a releasable fixation member releasably fixing the vascular graft to a distal end of the inner sheath (Fig 16 Item 235), an expandable member expandable from a contracted position closely proximate an exterior of the delivery sheath to an expanded position urging the vascular graft against the wall of the body cavity (Fig 15 Item 210), the expandable member is positioned at a distal end of the delivery sheath (Fig 10 Item 210), and the expandable member has a distal end thereof shaped in the expanded position to conform to a shape of the delivery members in the deployment position (210). At the very least, it is well known to have guide wires in these systems. The guide wire would have its own lumen enclosing the guide wire to keep it stable and in position. This would be a sheathed guide wire. The device would encircle the guide wire placing the delivery members around the inner sheath. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Strecker's fixation

system to include Miller's inner sheath and expandable member. Such a modification would restrain the delivery members until deployment, fix the graft until deployment preventing undesirable release, and a balloon to ensure full expansion of the graft.

Response to Arguments

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is

(571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

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